DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

95149d

WARNING LETTER

December 9, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Joni L. Walton
President
Danlee Medical Products, Inc.
6075 East Molloy Road
Rodax Park / Suite #5
Syracuse, New York 13211

Ref: NYK-2005-01

Dear Ms. Walton:

During an inspection of your firm located in Syracuse, New York, conducted September 1st, 2nd & 3rd, 2004, our investigator determined your firm manufactures a medical device under the brand name of "E-Clip & Custom Hook-Up Kits". This is a single use device used as an accessory to electrodes. The firm also assembles the Custom Hook-Up Kits which are commonly referred to as, "Holter Kits". These kits are devices within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

These devices identified as the "E-Clip" and the "Custom Hook-Up Kits" are adulterated within the meaning of Section 501(h) of the Act, in that, the methods used in, or the facilities or controls used for the manufacturing, packaging, storage, or installation are not in conformance with good manufacturing practices, as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 820, Quality System Regulations as follows:

1) Failure to establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured and to establish quality system procedures and instructions as required by 21 CFR 820.5 and 21 CFR 820.20(e).

   Specifically, the firm's management has not defined, documented and implemented procedures to ensure and verify the firm's quality system has been correctly established and implemented throughout the entire organizational structure.

2) Failure to establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100(a). These CAPA activities were also not defined and documented as required by 21 CFR 820.100(b).

3) Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70(a), and failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications as required by 21 CFR 820.70(a).

   Specifically, the processes for production of the Custom Hook-Up Kits lacked written procedures to ensure conformance to specifications.

4) Failure to maintain complaint files and complaint handling procedures for receiving, reviewing and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a), and failure to maintain procedures to ensure that complaints are evaluated to determine whether the complaint represents and event which is required to be reported under parts 803 or 804 of the Chapter, Medical Device Reporting (MDR) as required by 21 CFR 820.198(a)(3).

   We acknowledge that on September 2, 2004, during the inspection, your firm established a complaint handling policy that addresses the evaluation of complaints received regarding possible MDR filings. Please note, however, that your policy fails to state when MDRs are to be reported to the FDA.

5) Failure to establish and maintain procedures for the identification, documentation, evaluation, segregation and disposition of nonconforming products as required by 21 CFR 820.90.

   Specifically, the Return Materials Authorization Policy, dated May 19, 1998, and the Return Materials Memo, dated October 25, 1999, do not address the control of non-conforming products to prevent the reoccurrence of distributed non-conforming products, nor the need to evaluate non-conforming product to determine the need for an investigation and notification of the persons or organization responsible for the non-conformance. We acknowledge that during the inspection, you provided the investigator with the Return Policy, dated September 2, 2004, and a RMA # / Complaint Log, for recording product information and the reasons for product returns. However, the Return Policy does not address the evaluation of non-conforming product. You stated that your September 2, 2004, RMA # / Complaint Log would be revised, but the revised document has not been submitted to FDA for review.

6) Failure to control labeling and packaging operations to prevent the possibility of labeling mix-ups during the manufacturing process, and failure to establish and maintain an adequately documented Device History Record (DHR) with procedures to ensure that the DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR) and its requirements as required by 21 CFR 820.120(d) and 21 CFR 820.184(e).

   Specifically, a review of eleven of the firm's DHR's for a six month period was conducted. This review revealed that eleven out of eleven DHR's contained deficiencies where the records did not include or refer to the location of the devices primary identification labeling.

Additionally, the devices are misbranded under section 502(o) of the Act, in that the devices were manufactured, prepared, propagated, compounded or processed in an establishment not duly registered under section 510 of the Act, and were not included in a list required by section 510(j) of the Act for medical devices.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence with each applicable requirement of the Act and the regulations. The specific violations noted in this letter and on the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food & Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which QSR/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to seizure, injunction and/or civil penalties.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the attention of Arthur S. Williams, Jr., Compliance Officer, Food & Drug Administration, New York District Office, 158 - 15 Liberty Avenue, Jamaica, New York 11433 – 1034, (718)662-5568.

Sincerely,

Jerome G. Woyshner
District Director
New York District